

(12) UK Patent Application (19) GB (11) 2020557 A

(21) Application No 7916667
(22) Date of filing
14 May 1979
(23) Claims filed
14 May 1979
(30) Priority data
(31) 2821048
(32) 13 May 1978
(33) Fed Rep of Germany
(DE)
(43) Application published
21 Nov 1979
(51) INT CL² A61B 17/50
(52) Domestic classification
A5R CX
(56) Documents cited
None
(58) Field of search
A5R
F2N
(71) Applicant
Willy Rüscher GmbH &
Co. KG
7053 Kernen iR
(Rommelshausen)
Germany

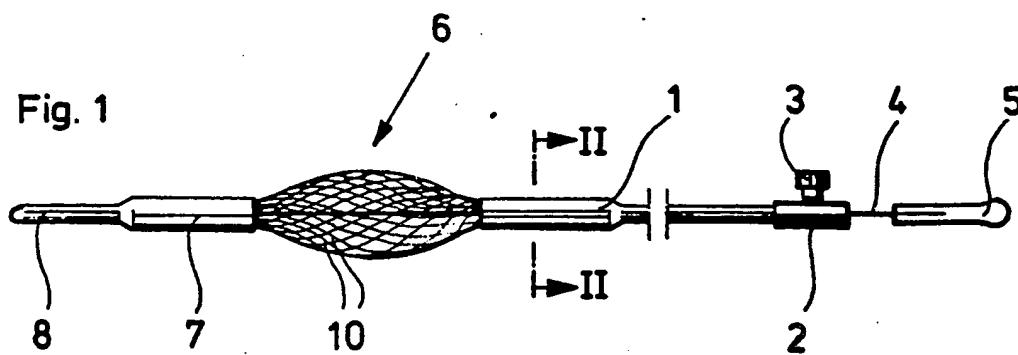
(Fed Rep)
(72) Inventor
Heinz Rüscher
(74) Agents
Wheatley & Mackenzie

(54) Medical instrument for removing foreign bodies

(57) This invention relates to a medical instrument for the removal of foreign bodies out of physiological channels, such as ureters, arteries, bronchi and suchlike, having a flexible tube 1 for insertion into the physiological channel involved, said tube having an operating element 5 at its operator end and an expandable element 6 at its insertion end, said expandable element being affixed at one end to the end of the tube 1 and at the other end to the end 8 of a controlling cable 4 and which via the controlling cable 4

which passes through the tube and which is connected to the operating element can be expanded and collapsed. The expandable element comprises a tube section made of a woven fabric or a braided fabric, the threads of which are spaced one from the other and which take an approximately screwthread-like course when the element is in the collapsed state. After insertion into the physiological channel, the element is expanded, it remaining permeable to fluids, but bearing foreign bodies with it on removal.

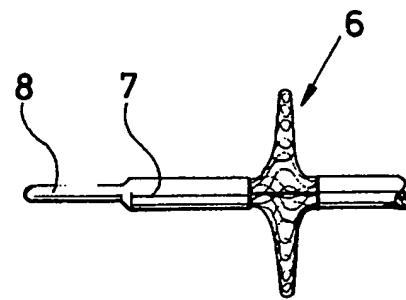
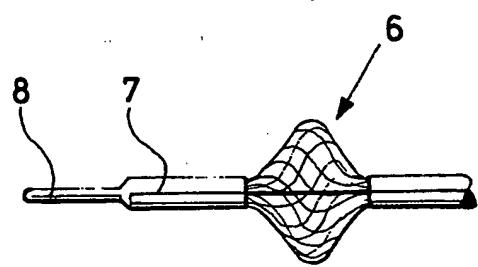
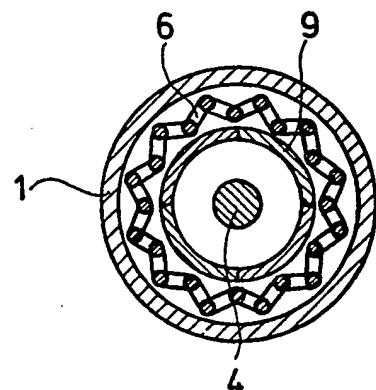
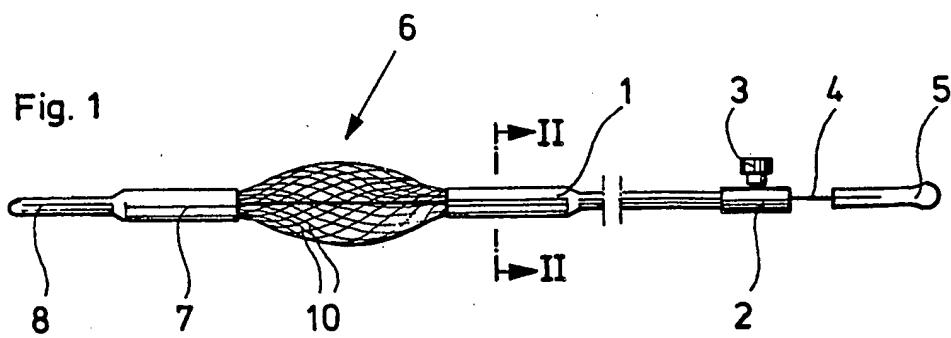
Fig. 1



GB 2020557 A

2020557

1/3



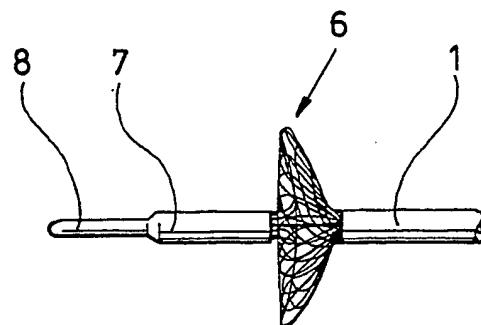


Fig. 5

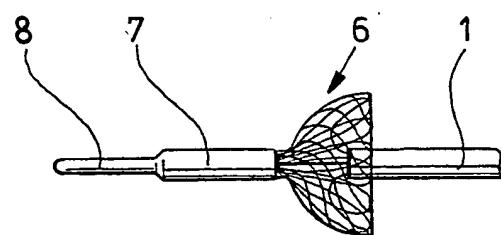


Fig. 6

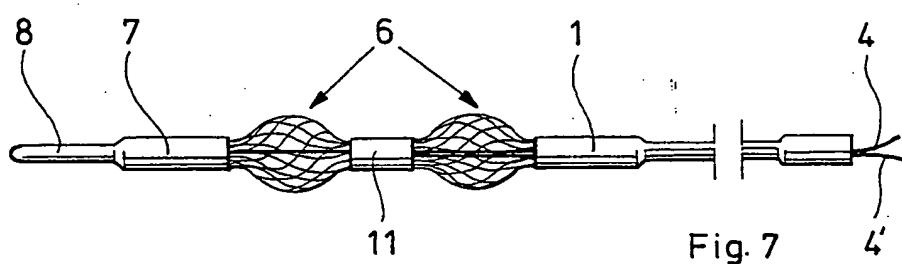


Fig. 7

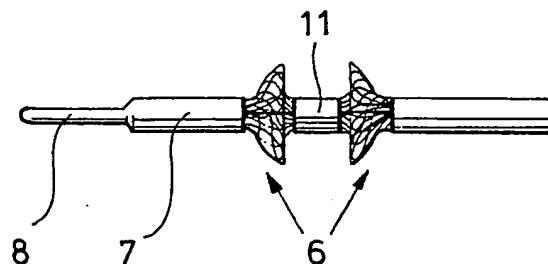


Fig. 9

2020557

3/3

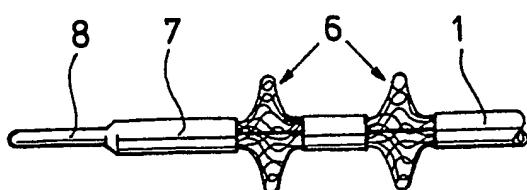


Fig. 8

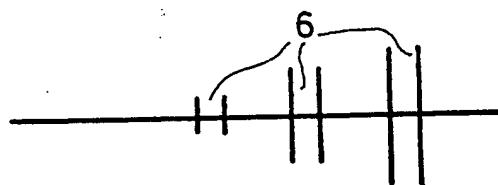


Fig. 10

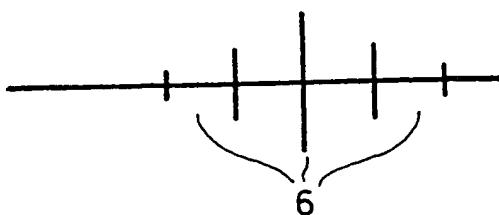


Fig. 11

SPECIFICATION

Medical instrument

5 The invention relates to a medical instrument for the removal of bodies out of physiological channels, such as ureters and biliary ducts, arteries, veins, bronchi, trachea and oesophagus and the like, which comprises a flexible tube for insertion into the physiological channel involved, the said tube having an operating element at its operator end and an expandable elastic element at its insertion end, the said elastic element being attached at one end 10 to the tip of the tube and at the other to one end of a controlling element, and which is expanded and collapsed by means of the controlling element which passes through the tube and is connected to the operating element.

15 Similar instruments in the form of fishbone extractors have been known for many decades. These well-known fishbone extractors comprise a tube, through which a flexible rod is passed which is provided with a ring at its operator end. The operator end of the tube is provided with a handle. At the insertion end of the tube, a ring of hog's bristles arranged in the longitudinal direction, that is, along 20 surface lines, is attached, the ends of the said bristles being bound together and affixed to the end of the flexible rod passing through the tube. For the facilitation of the introduction of the instrument, a small, spherical piece of 25 sponge or a rounded rubber or metal head is affixed to the free end. By applying traction to the ring-shaped operating element, the practically stretched hog's bristles, which are only slightly curved outwards and form a kind of 30 tube, are bent and, in consequence, more strongly curved outwards until they form a sort of sphere. In consequence of this operation, the fishbone to be removed from the oesophagus becomes graspable and can be 35 captured between the hog's bristles and removed, removal being effected by complete or partial release of the operating element, thus effecting the relaxation of the hog's bristles and their resilient return to an original shape.

40 45 50 (Rüschi-Katalog of 1910, pages 48, 49). Further, an instrument for the removal of foreign bodies out of physiological channels is also known (DE-PS 10 99 126), which comprises a flexible small-bore tube, through 55 which a controlling element is passed, the said controlling element being provided with an operating member at the operator end. At the insertion end, a bushing is attached to the controlling element, into which bushing a 60 number of spring wires wound in the form of screw threads are inserted, the free ends of which engage in a pointed-arch-shaped head, in which they are fixed. By applying traction to the operating element, the spring wires are 65 drawn into the tube. After insertion of the

instrument into the physiological channel, the operating element, which is located at a distance from the operator end of the tube, is shifted towards this end of the tube, with the

70 result that the spring wires emerge from the end of the tube and, owing to their springiness, form themselves into a basket which, in profile, takes up an onion-like form, the said basket being capable of accepting a 75 kidney stone or other foreign body. By partially pulling back the operating element, the basket is caused to narrow and made to close round the foreign body which can subsequently be removed by withdrawing the tube.

80 Gall stone extractors are also known (Rüschi-Katalog No. 328000), which comprise a flexible tube, at the insertion end of which a balloon is affixed, the said balloon being inflatable via the tube by employing a Luer Lok 85 syringe or something similar. The extractor is introduced into the physiological channel, for example, into the ureter, until the balloon is located beyond the stone to be removed. Following the inflation of the balloon, the 90 stone is released by the dilatation thus caused and can be removed by withdrawing the extractor.

Finally, a universal embolus and thrombus extractor is also known (Rüschi-Katalog No. 95 327000), which is essentially identical in its construction to, differing merely in its dimensions from, the previously mentioned gall stone extractor. It serves to remove thrombi and emboli from arteries or veins.

100 The objective of the present invention is to provide an improved, universally employable instrument for the removal of bodies out of physiological channels, which can be employed by the physicians without any problem.

105 This objective has been achieved by this invention starting from a medical instrument of the type mentioned initially by the use of an expandable element constituted by a woven-fabric or braided-fabric tube section, the individual threads of which are spaced, one from the other, and which, when the element is in the collapsed state, are twisted, partially to the right, partially to the left, in an approxi- 110 mately screwthread-like manner.

In this (viewed retrospectively) surprisingly simple manner, it has been possible to produce a universally employable medical instrument for the removal of foreign bodies out of 115 physiological channels, which, depending upon its dimensions, can be employed to advantage for a wide range of different purposes. On the one hand, it can serve as a fishbone extractor and can equally be used for 120 the removal of gall stones and the like. In the latter case, a particular advantage resides in the fact that neither the capture of the stone in a basket is required—a manouvre requiring considerable luck and skill—nor is there any 125 130 risk of the balloon of the extractor being burst

by a sharp-edged stone. In the case of the instrument of the invention it is, namely, of advantage that, in consequence of the expansion of the expandable element, an umbrella 5 is formed which not only dilates the physiological channel and thus results in an easier release of the stone, but which also manifests no tendency to wedge the stone in the acute angle between the balloon and the wall of the 10 channel, but rather, in the manner of a snowplough, pushes the stone before it. In consequence, the handling of the instrument of the invention is extremely simple, with the result that the chances of achieving success 15 with the manouvre are very much increased and the risks to the patient considerably reduced. However, the instrument of the invention is also equally suitable for the removal of thrombi and emboli out of veins and arteries, 20 the already mentioned snowplough effect being of great advantage. Finally, a further advantage resides in the fact that the collapsed element manifests a relatively small diameter, while the expanded element manifests a multi- 25 pply enlarged diameter. The unexpanded element is very elastic and the expanded element surprisingly rigid and resistant to distortion. Moreover, in some applications an additional advantage lies in the fact that the expandable 30 element, whether in the collapsed or ex- panded state, manifests a grid-like structure, which permits the passage of fluids.

The introduction end of the instrument can take various forms. For example, the introduction end can be formed by a fusion of the 35 threads forming the woven or braided section of the tube. The end of the controlling element passes into, and is attached to this fused head, for example by melting. In the case of 40 other preferred embodiments of the invention, however, a small-bore tube having a closed, rounded free end, is pushed over the insertion end of the controlling element and flexible tube section. Both embodiments have the 45 advantage of permitting the easy introduction of the instrument in the form known from catheters and familiar to every physician.

As the controlling element, preference is given to a spring wire. Such a wire is, on the 50 one hand, adequately stable while, on the other hand, being sufficiently formable. In addition, it offers the advantage of conferring X-ray opaqueness on the medical instrument, which means that the physician can establish 55 the depth of insertion of the instrument and the course it has taken, or the location of the insertion end within the body of the patient.

The tube can be made of various different materials. Preferentially, it is made of a plastic 60 material. In a more advanced embodiment of the invention, a helical spring is inserted to stiffen the tube and provide a guideway for the controlling element. Nevertheless, the tube is elastically formable. Its construction is 65 comparable to the outer sheathing of a Bow-

den cable.

In particular in the case of a relatively long and very thin instrument, such as is required, for example, for the removal of thrombi and emboli, the manufacture of the instrument can give rise to difficulties. Therefore, in the preferred versions of the invention, the tube is constructed in the form of a shrink-down plastic tubing. In consequence of its enlarged 75 diameter, this tubing can be easily pushed over the helical spring sheathing, to which, after appropriate heating and resulting shrinking, it approximates tightly and virtually jointless.

80 In a preferred embodiment of the invention, the medical instrument is provided with more than one expandable element and the individual expandable elements are arranged at a distance from one another. This embodiment 85 of the invention has considerable advantages. For example, it makes it possible to capture a foreign body between two expanded elements as in a cage, and to push it along the physiological channel. During this process the leading expanded element, by virtue of its snowplough effect, removes other depositions or bodies located within the channel which might make the removal of the foreign body in the cage difficult or, by conglomerating 95 with the foreign body, even prevent its removal altogether. Finally, when expanded, the expandable elements can manifest differing diameters, which, in particular, can increase progressively in one direction. This feature, 100 too, can lead to a more reliable and certain action of the instrument of the invention, when the elements are appropriately dimensioned.

The constructive design of the instrument 105 with several expandable elements, can take varying forms. For example, a separate controlling element can be associated with each expandable element, each controlling element being provided with its own separate operating element. This design, however, both requires a relatively complicated construction—and thus is expensive in its manufacture—and also results in a relatively complicated form of application. In the preferred 115 embodiments of the instrument of the invention, therefore, a stiff section of tube is provided between the expandable elements, and the expandable elements are expandable by means of a common controlling element 120 which is connected to the expanded element closest to the insertion end. The traction applied to the introduction end by the controlling element acts, via the nearest expandable element and the following section of tube, 125 upon the next expandable element and causes all the expandable elements to become expanded in the same manner.

In preferred embodiment of the invention, the woven or braided material has a mesh size 130 which is some three to ten-fold greater than

the thickness of the threads forming the woven or braided fabric. Such a relationship of dimensions results in the expandable element having good qualities of formability coupled with an adequate permeability and, on the other hand, an adequately small mesh for the removal of even relatively small bodies or foreign bodies. The small mesh of the expanded element results, in particular, from the fact that the "umbrella" created by expansion, comprises two woven or braided layers in contact with each other, with the result that the effective mesh size is reduced. The relatively large mesh size of the unexpanded element offers the advantage of high flexibility. In the unexpanded element, the mesh spaces adopt a rhomboid shape, of which the diagonal parallel to the longitudinal direction of the instrument is very much greater than the diagonal arranged tangentially to the tube. The individual threads run substantially along a helical line, account having to be taken of the fact that the tube section has no constant diameter in the longitudinal direction, but manifests a diameter which increases somewhat from the ends towards the middle. When expanding the element, the individual threads move relative to one another, and the length ratio of the two diagonals of each rhombic shape alters until, in a mean position, the rhombic shapes have become substantially square. On being further altered in shape, the expandable element forms a circular disc comprising two layers of material under initial tension, the centre of the disc merging, funnel-like, into the neighbouring end of the tube. The funnel adopts the form of the whirlpool seen at a water-drain hole. In this expanded position, the threads adopt a substantially circular contour in the region in which they form the disc. The form of the mesh spaces can deviate from the form just described if other fabric weaves are used as will be described in more detail later.

In preferred embodiments of the invention, the weave or braid consists of plastic-material threads, in particular, solid polyester, polyamide or PVC threads. The use of solid threads in preference to spun or braided threads provides the advantage of improved mobility of the threads with respect to one another, with the result that the change of shape and return to the original shape of the expandable element is favoured.

However, as in other embodiments, the woven fabric or braided fabric can be made also of a natural material, in particular silk, linen or cotton. (silk is obtained from the insides of the silkworm).

The weave of the woven fabric or braided fabric can take various forms. For example, either a plain weave or a satin weave can be employed. In the preferred embodiment of the invention, however, the woven fabric or the braided fabric is of twill weave and, in particu-

lar is a K₂² weave. This weave has proved particularly successful, since it permits ready deformation of the expandable element and, on the other hand, provides a good returning force. In addition, at the same time, favourable mesh widths can be realized.

The non-expanded element, preferably manifests the same shape as the unexpanded fishbone extractor, that is, the shape of a spindle or a tube having a somewhat greater diameter in the middle. Nevertheless, without there being any change in the outer appearance of the unexpanded element, it is possible for the expanded element to have differing shapes. In general, it takes the already described shape of a disc ending on either side in a funnel. The expanded element is symmetrical to a plane passing through the middle of the disc, the plane being traversed centrally and perpendicularly by the tube and the controlling element. In other preferred embodiments of the invention, however, the expandable element is an expansion, arranged unsymmetrically with respect to a transverse central plane, and in the expanded state takes the form of an opened umbrella. Thus, the two contacting or neighbouring surfaces of the braided or woven fabric which, in the expanded state extend from a circular outer common margin, are not domed in opposing directions, but in one and the same direction. In this condition, the open side of the dome or vault can face the insertion end. Preferably, however, the expanded element presents a concave umbrella shape, the opening of which faces the operator end. This has the advantage that, when removing foreign bodies, the latter show a tendency to move towards the middle of the umbrella, that is, away from the wall of the physiological channel. This not only facilitates the removal procedure, but also, for example, prevents any damage being done to the wall of the physiological channel during the removal of sharp-edged stones from relatively narrow channels. Thus, the expandable element spread into an umbrella-like shape not only dilates the channel locally and reversibly, but, at the same time, also ensures that the foreign body is kept at a distance from the wall of the channel.

The realization of the expandable element in such a way as to result in an umbrella-like shape in the expanded state, is effected by a type of mechanical memory of the woven-fabric or braided-fabric tube section. This mechanical memory can, for example, be induced by means of a constrained mechanical deformation during the initial expansion. However, a thermal treatment can also be carried out either in place of or additional to this mechanical treatment. It would also be possible to produce the braided fabric using yarn or threads tapering in one direction, so that in this manner a preferential deformation might

be achieved. Admittedly, the manufacture of a braided fabric employing tapering yarn or threads would be very complicated and expensive, so that the previously explained methods 5 are preferably employed.

Further details and improvements of the present invention will be obvious from the following description and the drawing showing embodiments explained herein, read in 10 conjunction with the claims. The figures are as follows:

Figure 1 a side view of an instrument of the invention with the element in the non-expanded condition,

15 *Figure 2* a cross-section taken along line II-II of Fig. 1,

Figure 3 the instrument shown in Fig. 1, with the element partially expanded,

20 *Figure 4* the instrument shown in Fig. 1, with the element completely expanded,

Figure 5 an instrument which, with unexpanded elements, is indistinguishable from the instrument shown in Fig. 1, with expanded element,

25 *Figure 6* an instrument with expandable element expanded to another shape,

Figure 7 an instrument with two non-expanded, expandable elements,

30 *Figure 8* the instrument shown in Fig. 7, with the elements expanded,

Figure 9 an instrument similar to that shown in Fig. 8, but with the elements unsymmetrically expanded, and

35 *Figures 10 and 11* schematically represented elements with numerous elements of different diameters.

The representation in the drawings is, in part, enlarged, in order the better to represent details.

40 The medical instrument illustrated in Fig. 1 comprises a flexible tube, 1, which is preferably made of plastic material and whose diameter can be between about 2 to 3 mm and 50 to 100 mm, depending upon the particular

45 application. At the operator end of the tube, 1, a locking means, 2, is provided, which comprises a bushing with a radially arranged screw, 3, with the aid of which a wire passing through the bushing and serving as a control-

50 ling element, 4, can be locked. At the free end of the controlling element, 4, there is an operating element, 5, which, for example, takes the form of a section of tubing or a small operating knob. At the opposite end of

55 the tube, 1, an expandable element, 6, is arranged comprising a tube-like section made of woven fabric or braided fabric, one end of which is introduced into the end of the tube, 1, whereas the opposite end is introduced

60 into, and affixed to, a hollow head piece, 7, the distal section of which is tapered, and the tip of which is rounded and closed off. Within the tube, 1, and also within the section of the expandable element, 6, located within the

65 tube, 1, there is arranged a helical spring, 9,

(Fig. 2), the closely neighbouring windings of which form a sort of tubular guideway similar to that seen in the Bowden cable. The controlling element, 4, which takes the form of a wire, extends to the head piece, 7, in which its end is affixed.

The woven-fabric or braided-fabric tube section that makes up the expandable element, 6, consists of twill-woven yarn 10, a K₂² 75 weave being preferably used. In this weave, each warp yarn passes over two filling yarns and then under two filling yarns while, vice versa, the filling threads pass in the same manner over two warp yarns and under two 80 warp yarns. Neighbouring warp and filling threads are displaced with respect to each other by one thickness. The yarns, 10, each comprise a single thread, that is, they are not made up of a number of twisted, braided or 85 woven or tangled threads. Preferentially, they are made of artificial material and manifest as smooth a surface as possible, so that, when the expandable element, 6, is made to change its shape, they can move relative to one 90 another. However, the yarns, 10, may also be made of natural fibres or silk.

If, by pulling on the operating element, 5, the controlling element, 4 is moved relative to tube, 1, that is, if the controlling element, 4 is 95 drawn out of the tube, 1, the end of the controlling element, 4, takes the head piece with it, so that the expandable element, 6, is expanded until it has attained approximately the form shown in Fig. 3. During this process, 100 the shape of the mesh formed by the threads, 10, changes. If the head piece, 7, is further moved towards the tube, 1, the configuration of the expandable element, 6, represented in Fig. 4 is finally attained, the outer diameter of 105 which is two- or several-fold the diameter of the non-expanded element, 6, (Fig. 1).

When employed, the instrument is inserted with the end, 8, leading into the physiological channel, for example, via the urethra and 110 bladder into the ureter, and advanced until the expandable element, 6, is located at the far side of the foreign body to be removed, for example, a gall stone or a kidney stone.

During this process, the position of the instrument can be monitored by X-ray means, since both the helical spring, 9, and the wire forming the controlling element, 4, are clearly imaged. Finally, by applying traction to, and then releasing, the controlling element, 4, for

120 as many times as might be necessary, the expandable element, 6, is expanded and collapsed in order to release the stone from the wall of the physiological channel. Finally, with the element, 6, in the expanded position, the 125 instrument is withdrawn, the expanded element, 6, bearing the stone with it.

For the removal of thrombi, that is clots of blood, or emboli, that is, droplets of fat, foreign bodies or the like, out of veins or 130 arteries, the instrument is introduced into the

appropriate vessel until the end, 8, penetrates through the thrombus or embolus and the expandable element, 6, is located beyond the embolus. Finally the element, 6, is expanded 5 until it is in contact over its circumference with the wall of the vein, the latter being dilated during the process, and then the instrument is withdrawn, the expandable element, 6, bearing the embolus with it.

10 By appropriate mechanical, thermal or chemical pre-treatment of the expandable element, 6, it is also possible to achieve expanded configurations such as are shown in Figs. 5 and 6. In particular, the arrangement 15 shown in Fig. 6 is especially suitable for the removal of foreign bodies, since with the shape of this embodiment, when the instrument is withdrawn, the body to be removed is collected up as in a basket, the circumferential 20 wall serving as a scraping means which loosens any particles adhering to the walls of the channel and causes them to move into the basket.

Multiple arrangements as shown in Figs. 7 25 to 11 are also possible. In such embodiments, the expandable elements can take on varying expanded forms and also differing expanded diameters.

A substantial advantage of the instruments 30 of the invention is the fact that they are highly universal in their application, and need to be matched to the physiological channel involved, only with respect to their dimensions, it also being possible to effect such a matching 35 by appropriately adjusting the degree of expansion of the expandable element. In many cases, the grid-like lattice structure of the expanded element, 6, is also of advantage, since it permits the passage of fluids 40 through it.

The instruments of the invention also make it possible to remove thrombi and emboli located at places that are difficult of access. They also make it possible to do away with 45 the insertion of filters into veins, for example the inferior vena cava, the use of which has occasionally led to complications owing to the fact that the inserted umbrella has come away from its anchorage and migrated through the 50 vein to the heart and through the heart into the pulmonary artery.

The Mobin-Uddin filter employed, for example in this case, then had to be removed by surgical means. If, instead of using such a 55 filter, a vena cava occlusion is carried out with the aid of a balloon, it can be observed that, over the course of several months, the balloon collapses, and it is not certain whether it is then held in situ by the vein. But, also in this 60 case, a permanently in-dwelling foreign body remains in the vein, which can give rise to disorders. The balloon cannot be made of silicone rubber, since this material is not adequately stable mechanically (tear propagation

great a permeability for gases. For this reason, it must be made of latex, to which softening agents and other additives are admixed which can separate out again and migrate through, 70 or distribute themselves throughout, the body of the patient. In contrast, the instrument of the invention can also be employed in such cases and removed again after several days. Such applications are found, for example, 75 following surgical operations, after accidents or in the case of patients confined to bed over lengthy periods of time, in whom thrombi frequently form, in particular in the veins of the legs. Such thrombi, when they become detached, pass via the heart into the arteries of the lungs, where they cause embolisms. In consequence of this, if such an embolism does not lead to death within a matter of seconds, larger or smaller areas of the lungs 80 are cut off from the circulation and an over-loading of the right heart, pneumonia and the like occur. Treatment of these pulmonary emboli is possible by means of lysis with the aid of Streptokinase at the very early stage. Further thrombi can, however, become detached within the deep veins of the legs and the veins of the pelvis, which thrombi can lead to further embolisms. In general, it is not possible 85 to reduce the clotability of the blood in freshly operated-on patients, since, then, the surgical wounds would start to bleed again. The treatment with Streptokinase can, however, be carried out only over a few days since then, an anti-reaction of the body eliminates 90 the effect of the Streptokinase again. Thus, a patient must be protected from further emboli both during the lysis of a pulmonary embolus and also subsequently, and this is why the already mentioned Mobin-Uddin filter 95 or a balloon has been used to occlude the vena cava. By employing one of the instruments of the invention, and with appropriate expansion, which can be fixed by locking the controlling element, 4, with the aid of the 100 screw, 3, the above-mentioned problem can be solved in a simple manner. The expanded element is permeable and blood can continue to flow through the vein. Any thrombi that might be carried along by the blood, are 105 captured by the expandable element and, when after a number of days the danger is past, the instrument, together with any captured thrombi, can be removed again, unless no lysis or breakdown has been achieved by 110 means of anti-clotting agents such as, for example, heparin or Streptokinase. Thus, no foreign body, which itself could represent an endangerment or could give rise to complications, remains for any lengthy period of time 115 within the body of the patient. The embodiments illustrated in Figs. 10 and 11, serve to produce a gradual dilatation of the physiological channel. On the basis of the increasing and, possibly, again decreasing series of di-

dilatation and, where applicable, re-narrowing of the channel can be achieved.

It is also possible, but not illustrated in the drawing, to pass a further thin tube or a thin length of tubing, through the flexible tube, 1, the thin tube or length of tubing terminating at one of the elements, 6, or in the head piece, 7. Through this thin tube or thin length of tubing, fluids or gases can be introduced or removed. Thus, for example, stone-dissolving or thrombolytic agents can be this manner be introduced. Equally, specimen of the patient's own body fluids can be obtained from the side of application of the expandable elements and, for example, employed for analytical purposes.

It goes without saying that the invention is not restricted to the embodiment examples represented here, but that deviations of these are also possible, without exceeding the framework of the invention. In particular, individual characteristics or features of the invention can be employed either alone or combined severally.

25

CLAIMS

1. A medical instrument for the removal of foreign bodies out of physiological channels, such as ureters and biliary ducts, arteries, veins, bronchi, trachea and oesophagus and the like, which comprises a flexible tube for insertion into the physiological channel involved, the said tube having an operating element at its operator end and an expandable elastic element at its introduction end, the said elastic element being attached at one end to the tip of the tube and at the other to one end of a controlling element, and which is expanded and collapsed by means of the controlling element which passes through the tube and is connected to the operating element, the expandable element comprising a woven-fabric or a braided-fabric tube section.

2. A medical instrument in accordance with claim 1, wherein a head piece having the form of a small tube with a closed, rounded free end is fitted over the insertion end of the controlling element and the expandable element.

3. A medical instrument in accordance with claim 1, wherein at the insertion end the threads of the woven-fabric or braided-fabric of the tube section comprising the expandable element are fused one with the other and that at the fused head, the end of the controlling element is affixed, for example, by melting.

4. A medical instrument in accordance with any one of claims 1 to 3, wherein a spring wire is employed as the controlling element.

5. A medical instrument in accordance with any one of claims 1 to 4, wherein the tube is stiffened by means of an inserted helical spring which forms a guideway for the controlling element.

6. A medical instrument in accordance with one of the previous claims, wherein the tube is formed from a shrink-on tube.

7. A medical instrument in accordance with one of the previous claims, wherein more than merely one expandable element is provided, and the individual expandable elements are provided in spaced arrangement.

8. A medical instrument in accordance with claim 7, wherein between the expandable elements a rigid tube section is provided, and the expandable elements are expandable by means of a joint controlling element which is connected to the expandable element in closest proximity to the insertion end.

9. A medical instrument in accordance with claim 7 or 8, wherein the expandable elements manifest, in the expanded state, varying and increasing diameters in one direction.

10. A medical instrument in accordance with any one of the preceding claims, wherein the woven fabric or braided fabric forming the expandable element manifests a mesh width which is three to ten times the thickness of the threads forming the woven fabric or the braided fabric.

11. A medical instrument in accordance with any one of the preceding claims, wherein the woven fabric or the braided fabric is made of threads or yarn of a plastic material, for example, solid polyester, polyamide of PVC threads or yarn.

12. A medical instrument in accordance with any one of claims 1 to 10, wherein the woven fabric or braided fabric is made of a natural material, for example, silk, linen or cotton.

13. A medical instrument in accordance with any one of the preceding claims, wherein the woven or the braided fabric is made in twill weave, for example, as K₂ weave.

14. A medical instrument in accordance with any one of the preceding claims, wherein the expandable element on being expanded, distorts unsymmetrically with respect to a transverse central plane of the controlling element and, in the expanded state, manifests the shape of an open umbrella.

15. A medical instrument in accordance with claim 14, wherein the expandable element forms a concave umbrella shape open towards the operator end.

16. A medical instrument, substantially as herein described with reference to and as illustrated in the accompanying drawings.

**This Page is Inserted by IFW Indexing and Scanning
Operations and is not part of the Official Record**

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- BLACK BORDERS**
- IMAGE CUT OFF AT TOP, BOTTOM OR SIDES**
- FADED TEXT OR DRAWING**
- BLURRED OR ILLEGIBLE TEXT OR DRAWING**
- SKEWED/SLANTED IMAGES**
- COLOR OR BLACK AND WHITE PHOTOGRAPHS**
- GRAY SCALE DOCUMENTS**
- LINES OR MARKS ON ORIGINAL DOCUMENT**
- REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY**
- OTHER:** _____

IMAGES ARE BEST AVAILABLE COPY.

As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.